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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,142	02/18/2004	Stephanos Kyrkanides	21108.0040U1	3987

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EXAMINER	
HAMA, JOANNE	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 09/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/781,142	KYRKANIDES, STEPHANOS	
	Examiner	Art Unit	
	Joanne Hama, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-132* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) *1-132* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Application was submitted February 18, 2004. Claims 1-132 have been filed and are under consideration in this Restriction.

According to the first paragraph of the specification, the Application that it is a continuation in part of PCT/US03/13672, filed on May 2, 2003, which claims priority to U.S. Provisional Application, 60/377,503, filed on May 2, 2002.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-43, 72-75, 83-91 drawn to a method of making and a composition comprising a nucleic acid, wherein the nucleic acid is a vector comprising a sequence encoding HEX-α, HEX-β, a promoter, an IRES, classified in class 435, subclass 320.1.

II-VIII. Claims 44-49, 61-66, drawn to method of transfecting with a vector and a composition wherein a cell is transfected with a vector of an effective dosage that reduces the effects of Tay Sachs or Sandoff's disease, classified in class 435, subclass 325. Claim 46 lists seven kinds of cells which can comprise the vector. Each cell is a separate invention:

II. neuron

III. glia cell

IV. fibroblast

V. chondrocyte

VI. osteocyte

VII. endothelial cell

VIII. hepatocyte

IX. Claims 50-60, 67-71, 76, 79-82, drawn to a composition wherein the animal comprises a vector, classified in class 800, subclass 3, or class 435, subclass 455+.

X. Claims 77-78, drawn to a method of producing a composition wherein the composition comprises a peptide, classified in class 536, subclass 23.1.

XI. Claims 92-114, drawn to a method of delivering a vector to a blood cell *in vivo*, classified in class 514, subclass 44.

XII. Claims 115-132, drawn to a method of delivering a vector to a brain cell *in vivo*, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Inventions II through VIII are to a method of transfecting cells and to a composition wherein a cell is transfected with a vector of an effective dosage that reduces the effects of Tay Sachs or Sandoff's disease. The Inventions have been separated into different Inventions by cell type (claim 46) because each cell is unique and each has a unique biological function. This requires separate searches in the art.

Inventions XIII and XIV while having the same class and subclass are have separated as different Inventions because they are different cell types. A

blood cell has a different function than a brain cell. This requires separate searches in the art.

Inventions I and II, III, IV, V, VI, VII, or VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). Invention I is to a method of making and a composition comprising a nucleic acid. Invention II, III, IV, V, VI, VII, or VIII is to a method of transfecting with a vector and to a cell transfected with a vector of an effective dosage that reduces the effects of Tay Sachs of Sandoff's disease. In the instant case, Invention I can also be used in an animal.

Inventions I and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). Invention I is to a method of making and a composition comprising a nucleic acid. Invention IX is to an animal comprising a vector. In the instant case, Invention I can also be used in cells.

Inventions I and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have

different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention I is to a method of making and a composition comprising a nucleic acid. Invention X is to method of making a peptide. Invention I is not required for Invention X and vice versa.

Inventions I and XI or XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). Invention I is to a method of making and a composition comprising a nucleic acid. Invention XI or XII is to a method of delivering a vector to a blood cell or a brain cell *in vivo*. In the instant case, Invention I can also be transfected into cells to make protein.

Inventions II, III, IV, V, VI, VII, or VIII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention II, III, IV, V, VI, VII, or VIII is to a method of transfecting cells and to cells comprising a vector with an effective dosage that reduces the effects of Tay Sachs or Sandoff's disease. Invention IX is to an animal comprising a vector. Invention II, III, IV, V, VI, VII, or VIII is not needed for Invention IX and vice versa.

Inventions II, III, IV, V, VI, VII, or VIII and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use

together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Inventions II, III, IV, V, VI, VII, or VIII is to a method of transfecting cells and cells comprising a vector with an effective dosage that reduces the effects of Tay Sachs or Sandoff's disease. Invention X is to method of making a peptide. Invention II, III, IV, V, VI, VII, or VIII is not needed for Invention X and vice versa.

Inventions II, III, IV, V, VI, VII, or VIII and XI or XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention II, III, IV, V, VI, VII, or VIII is to a method of transfecting cells and cells comprising a vector with an effective dosage that reduces the effects of Tay Sachs or Sandoff's disease. Invention XI or XII is to a method of delivering a vector to a blood cell or a brain cell *in vivo*. Invention II, III, IV, V, VI, VII, or VIII comprises cells *in vitro* and Invention XI or XII is to a method of delivering a vector to a blood of brain cell *in vivo*. The methods used to raise cells *in vitro* are different from the methods used to raise cells *in vivo*. Invention II, III, IV, V, VI, VII, or VIII does not require Invention XI or XII to function and vice versa.

Inventions IX and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention IX is to an animal comprising a vector.

Invention X is to a method of making a peptide. Invention IX does not require Invention X to function and vice versa.

Inventions IX and XI or XII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). Invention IX is to an animal comprising a vector. Invention XI or XII is to a method of delivering a vector to a blood cell or a brain cell *in vivo*. Invention IX can be made by methods other than that encompassed by Inventions XI or XII.

Inventions X and XI or XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention X is to a method of making a peptide. Invention XI or XII is to a method of delivering a vector to a blood cell or a brain cell *in vivo*. Invention X does not require Invention XI or XII to function and vice versa.

Claims 3, 6, 17-25, 87-91 generic to a plurality of disclosed patentably distinct species comprising promoters. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. The Applicant lists a constitutive (CMV and beta-actin), a cell specific (nuclear enolase), and an inducible promoter.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction

requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, divergent subject matter, and the different searches required for each Invention, restriction for examination purposes as indicated is proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is (571) 272-2911. The examiner can normally be reached on Monday-Friday 9:00-5:00.

Joe Woitach
AU1632

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, Ph.D. can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JH